REMARKS

In the Office Action mailed August 27, 2002, the Examiner rejected Claims 1-13 under 35 U.S.C. § 102(b) as being anticipated by Sweezer et al. (U.S. Patent No. 5,478,309)("Sweezer"). Applicant respectfully traverses the rejection.

Applicant respectfully submits that Sweezer fails to teach Applicant's invention as claimed in Claims 1-13.

Sweezer is directed to a device that is used in obtaining total cardiopulmonary bypass support and isolation of the heart during performance of a heart surgery, "The present invention is directed to a catheter system and method for achieving total cardiopulmonary bypass of the heart during heart surgery with provisions for proximal aortic occlusion, aortic root cardioplegia delivery, aortic root venting, and left venticular decompression. The system comprises a cardiopulmonary bypass pump which has an inlet port for reception of oxygen depleted blood from the venous circulation, and an outlet port for the delivery of oxygen-rich blood to the arterial circulation." (Sweezer, col. 5, lines 47-56.)

Sweezer can also be used to deliver a cardioplegia solution to the heart, "To deliver cardioplegia solution, a first proximate port on the cannula communicates with the first lumen and the cannula contains an orifice adjacent its distal end which is in communication with the first lumen thereby defining a single flow path for either the passage of cardioplegia solution or for the evacuation of fluid from the aortic root." (Sweezer, col. 5, lines 62-28.)

Sweezer allows for the selection of either the flow of cardioplegia solution or evacuating fluid from the aortic root through the single flow path.

Sweezer discloses a number of embodiments of how a cardioplegia solution may be perfused into the aortic root. One example is shown in Figs. 15-19, "Each of the

arterial perfusion catheters described in Figs. 15 through 19 embody an extended distal portion which may be extended across the aortic valve and into the left ventricle to provide a left ventricle venting function; cardioplegia solution may still be delivered into the aortic root as in the above-described embodiments of the arterial perfusion catheter or the same flow path may be used for aspiration of the aortic root." (Sweezer, col. 17, lines 9-18.)

The cardioplegia solution in this embodiment is introduced through the orifices marked 91'' which are located below the balloon catheter labeled as 27 (see Fig. 15). Sweezer does not disclose a collection means for the cardioplegia solution. Therefore, the solution will be free to flow throughout the cardiopulmonary system.

Sweezer discloses and illustrates another embodiment illustrated in Fig. 21, where the " ... distal tip 128 has a plurality of orifices 136 for delivering a cardioplegia solution into the coronary artery for arresting the heart." (Sweezer, col. 20, lines 45-48.) Sweezer does not disclose a collection means for the cardioplegia solution in this embodiment either. Therefore, the cardioplegia solution will be free to flow into the coronary arteries, the left ventricle and atrium, and the remainder of the cardiopulmonary system.

Another embodiment of the catheter is illustrated in Fig. 27, where, " ... a cardioplegia solution may be injected into the aortic root for flow into the coronary arteries to arrest the heart . . . the multiplicity of venting orifices 191 located adjacent to inflatable balloon 127' permit either the infusion of the cardioplegia solution or venting of the aortic root." (Sweezer, col. 22, lines 16-23.) Again, Sweezer does not disclose a collection means to keep the cardioplegia solution from flowing throughout the rest of the cardiopulmonary system.

Sweezer illustrates another embodiment in Fig. 38 where arterial venting orifices 291 are utilized for the injection of the cardioplegia solution into the aortic root. (This embodiment is also illustrated in Fig. 39.) Again, Sweezer does not disclose a means to collect the cardioplegia solution to prevent it from flowing into the rest of the cardiopulmonary system.

Sweezer does disclose a number of embodiments of a collection catheter. However, this catheter is not used for the collection of the cardioplegia solution that is used to stop the heart, but the collection catheter is used to collect de-oxygenated blood from the venous system. That collected blood is then fed through a cardiopulmonary bypass system where it is oxygenated and re-inserted as oxygenated blood in the aorta to bypass and isolate the heart for surgical procedures.

Applicant respectfully submits that independent Claim 1 and dependent Claims 2-13 recite the limitations of, "a collection conduit for acquiring the administered fluid, the collection conduit positioned adjacent to or into one of the downstream channels and having a collection seal for occluding external fluid flow." Sweezer does provide for a delivery conduit for delivering a cardioplegia solution to the heart, but does not disclose a collection conduit for collecting the cardioplegia solution, where the collection conduit is positioned adjacent to or into one of the downstream channels and has a collection seal for occluding external fluid flow.

Applicant respectfully requests that the Examiner withdraw the rejection to Claims 1-13 under 35 U.S.C. § 102(b).

In the Office Action, the Examiner rejected Claims 48-51, 53-56, and 59-60 under 35 U.S.C. § 102(b) as being anticipated by Glickman (U.S. Patent No. 5,817,046) ("Glickman"). To the extent that the rejection applies to the amended claims, Applicant respectfully traverses the rejection.

Applicant respectfully submits that independent Claim 48 and dependent Claims 49-60 recite the limitations of a system for fluid isolation in a biological mass, having a separate collection conduit positioned adjacent to or into a downstream channel, where the collection conduit has a collection seal for occluding external fluid flow, where a fluid is administered to the biological mass through a delivery conduit, and reclaimed by the collection conduit. Applicant respectfully submits that Glickman does not teach or suggest the desirability of the limitations as recited in independent Claim 48.

Applicant respectfully submits that Glickman teaches "isolating" the entire abdominal and pelvic regions, and the upper thigh above the tourniquets. Applicant respectfully submits that the entire abdominal and pelvic regions, and the upper thigh above the tourniquets of Glickman is not a "biological mass" as recited in independent Claim 48 and dependent Claims 49-60. Glickman accomplishes this "isolation" via aortic occlusion catheter 4 and vena cava occlusion catheter 3, and bilateral thigh tourniquets 8. (Glickman, col. 14, lines 10-13.) Glickman then injects a chemotherapeutic agent into the aorta and the vena cava via aortic occlusion catheter 4 and vena cava occlusion catheter 3. (Glickman, col. 14, lines 13-17.) Glickman discloses that the infused blood is passed via the common iliac vein to the common iliac vein catheter 9. (Glickman, col. 14, lines 17-19.) However, Glickman fails to disclose that the infused blood will also travel throughout the entire abdominal and pelvic regions, and the upper thigh region above the tourniquets and below the occlusions in the aorta and vena cava. Applicant is submitting herewith plates 292 and 300 from Netter's *Atlas of Human Anatomy* showing the vasculature of the pelvic and abdominal regions to show some of the veins and arteries and adjacent tissue that would be contaminated with infused blood when practicing the invention of Glickman.

In addition, Applicant respectfully submits that Glickman does not teach or suggest the desirability of a collection seal on the collection conduit. Applicant respectfully submits that Glickman does not achieve fluid isolation in a biological mass since the fluid that is administered to the biological mass through the delivery conduit is not reclaimed by the collection conduit. In the system disclosed in Glickman, the entire abdominal and pelvic regions, and the thigh above the tourniquets and below the occlusions in the aorta and vena cava are contaminated by the chemotherapeutic agent.

Applicant respectfully requests that the Examiner withdraw the rejections to Claims 48-51, 53-56, and 59-60 under 35 U.S.C. § 102(b).

In the Office Action, the Examiner rejected Claims 52 and 57-58 under 35 U.S.C. § 103(a) as being unpatentable over Glickman. Applicant respectfully traverses the rejection, and respectfully submits that dependent Claims 52 and 57-58 are allowable for at least the same reasons as allowable Claim 48 discussed above.

Applicant respectfully requests that the Examiner withdraw the rejection to Claims 52 and 57-58 under 35 U.S.C. § 103(a).

Attached hereto is a marked-up version of the change made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE".

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly, extension of time fees.

Respectfully submitted,
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Dated: 10/21/02

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CERTIFICATE OF MAILING:

I hereby certify that this correspondence is being deposited as First Class Mail with the United States Postal Service in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on October 21, 2002.

Nedy Calderon 10/21/02
Nedy Calderon Date

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN THE CLAIMS

The claims are amended as follows:

48. (Amended) A system ~~for fluid isolation in a biological mass having at least one upstream channel and at least one downstream channel,~~ comprising:

a delivery conduit positioned adjacent to or into ~~one of the~~an upstream channels of a biological mass;

a separate collection conduit positioned adjacent to or into ~~one of the~~a downstream channels of the biological mass, the separate collection conduit comprising ~~and having~~ a collection seal for occluding external fluid flow; and

a fluid to be administered to the biological mass through the delivery conduit, and reclaimed by the collection conduit, wherein the system is adapted for fluid isolation in the biological mass, where the biological mass has at least one upstream channel and at least one downstream channel.